Study Group 2: GHTF Progress Report

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Global Harmonization Task Force: Study Group 2

Mission: The purpose of a vigilance and postmarket surveillance system is to improve the protection of the health and safety of patients, users, and others by reducing the likelihood of the same type of adverse incident being repeated in different places at different times.

Global Harmonization Task Force: Study Group 2

- Charge: vigilance and postmarket surveillance
- Initial focus: vigilance
- All systems currently based on some form of manufacturer reporting to Competent Authority

SG2: Major Tasks

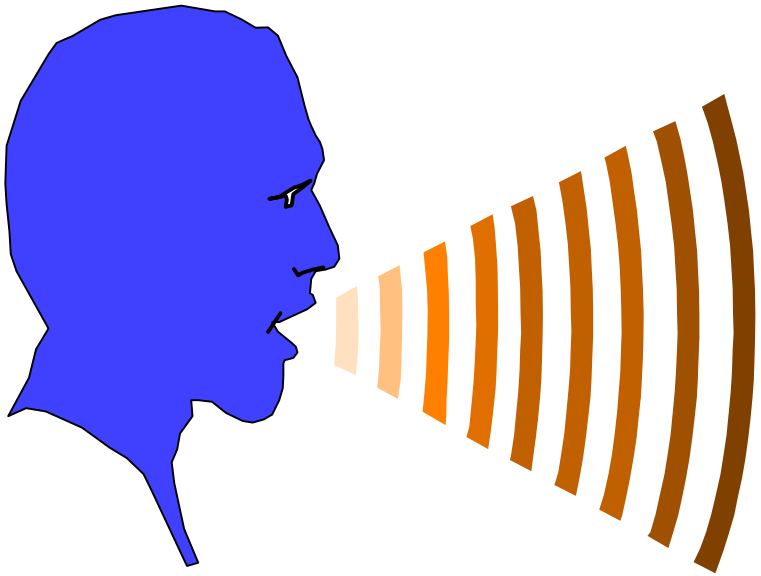
- Comparison of regulatory systems
- Types of events that require reporting
- What information is reported
- When and to whom reports are made
- Analysis of reports prior to dissemination
- Transmission of reports between CAs
- Nomenclature systems for reporting
- Postmarket surveillance studies

SG2: Major Documents

- Umbrella document/Precis (L. Kessler/USFDA)
- Regulatory comparisons (B. Khosravi/NEMA)
- Minimum data set (K. Kopesky/HIMA)
- CA to CA reporting (J. Nordan/Norway CA)
- Vigilance case definition (K. Dix/Candian CA)
- Standardized decision rules for reporting (L. Kessler/USFDA, I. Campbell/EU-Industry, and R. Gerard, EU-Industry)

THIS DID NOT WORK:

AN IMPORTANT CAUTION



- THE DECISION TREE DEVELOPED BY SG2 IS MERELY AN AID TO HELP INTERPRET SG2's HARMONIZED RULES FOR AE REPORTING **- IT CAN NOT BE USED BY ITSELF!!!**

SG2: Basic Reporting Structure

- Incident must meet three criteria
  - Event occurred or information received
  - Event/information related to mfr. Device
  - Death or serious injury did occur or could have occurred if event reoccurs
- Special cases
  - Significant public health issues
  - Change in trend of exemptions to reporting
- Exemptions for reporting

SG2 rules: Do not report if:

- Out-of-box failure that would always be detected
- AE due solely to patient condition
- AE due solely to end of life of product - documented in file
- Adequate single fault worked **- no injury**
- Remote probability of AE **- no injury**
- Expected, foreseeable AE -labeled and documented
- AE described in an advisory notice/recall
- Specific exemption granted by NCA

SG2 rules: Use Errors

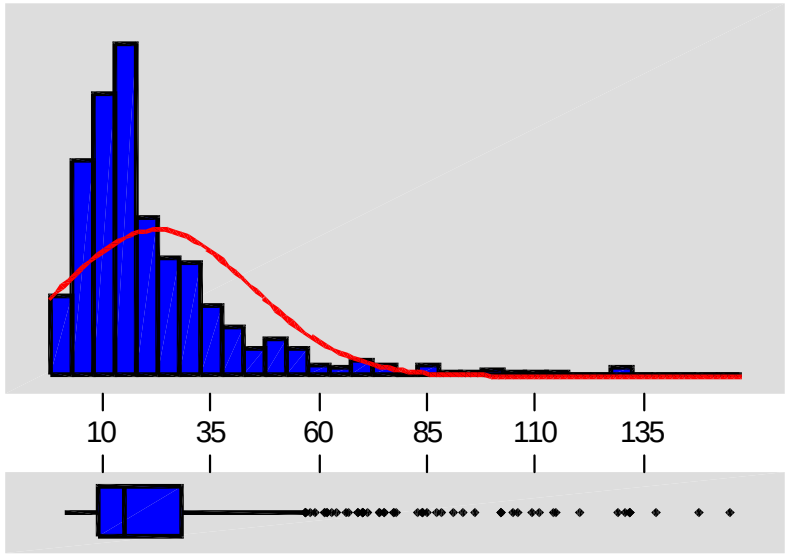
- The term use error covers unintentional and intentional misuse
- Reporting use error not yet globally harmonized
- Reporting across jurisdictions may be required
- Manufacturers should, at a minimum, report use error voluntarily

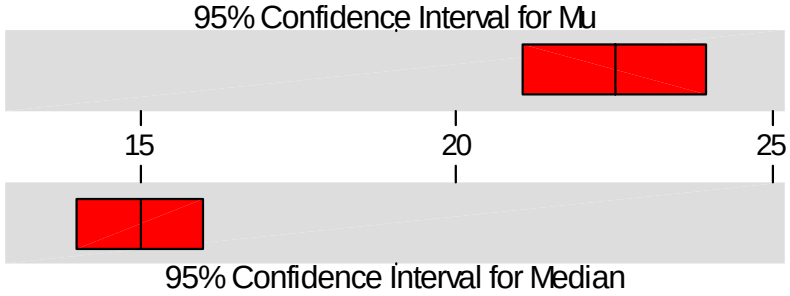
Getting Down to the Nitty Gritty

- **Reporting timeframes**
  - Two types of reports?
  - What does immediate mean?
  - Is a 30-days reasonable for a complete investigation? Data, please!
  - When does the clock start (define “becomes aware”)?
- **Data in AE reports**
  - Concept of the minimum data set
  - Considerations for developing a universal data set
- **Reuse of single use:**
  - Who reports under what conditions?
- ***Standard disclaimers***

Time Required to Complete Risk Assessment Investigations Related to Product Complaints

Descriptive Statistics





Variable: DAYS

Anderson-Darling Normality Test

A-Squared:	59.854
P-Value:	0.000

Mean	22.4994
StDev	21.9739
Variance	482.852
Skewness	2.58088
Kurtosis	8.54208
N	879

Minimum	1.000
1st Quartile	9.000
Median	15.000
3rd Quartile	28.000
Maximum	155.000

95% Confidence Interval for Mu

21.045	23.954

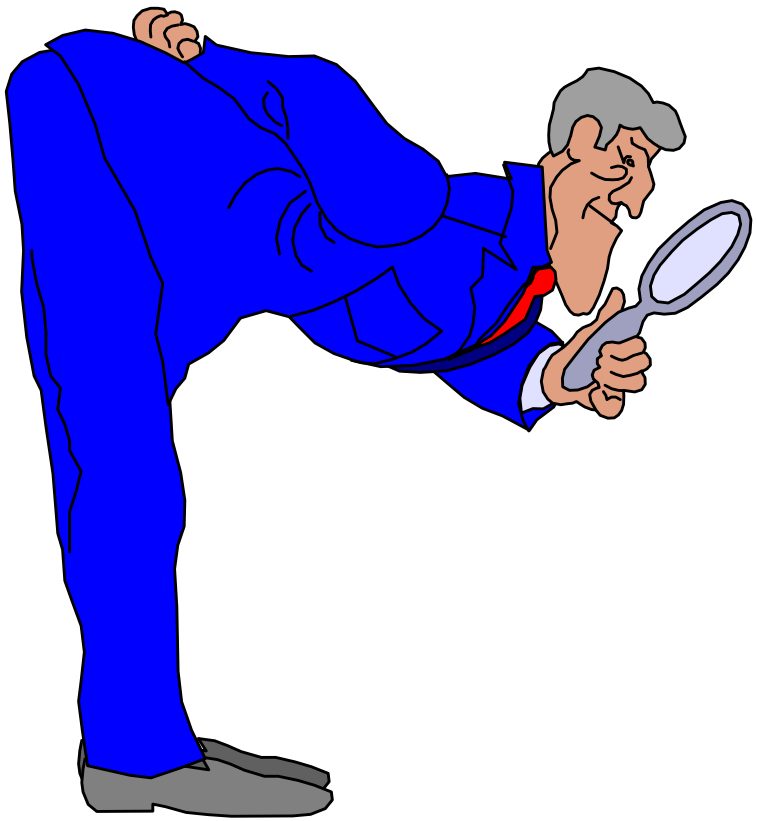
95% Confidence Interval for Sigma

20.993	23.052

95% Confidence Interval for Median

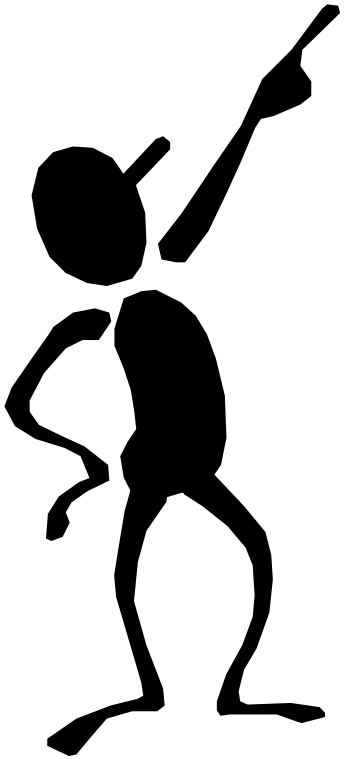
14.000	16.000

Pilot Tests: Examining our Work



- Pilot test of Vigilance Exchange HAS BEGUN: EU (UK, Germany, Norway), U.S., Canada, Japan and Australia
- Pilot test of SG2 Harmonized rules for reporting: an opportunity for industry

Next Steps for SG2



- Further AE refinement: Guidance, definitions
- Summary or periodic reports
- Electronic data interchange
- Integration with Q.S.R.
- Postmarket surveillance
  - **The systematic evaluation of marketed products; who determines need, what do the studies entail?**

Obstacles to SG2 Success

- Getting true buy-in from regulators who will have to make some changes
- Getting industry to investigate feasibility of SG2 products
- Education toward a common vision